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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	2820-4428.2US	6427
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TRASKBRITT, P.C.				
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SALT LAKE CITY, UT 84110				
EXAMINER				
CHIEN, STACY BROWN				
ART UNIT		PAPER NUMBER		
1648				
NOTIFICATION DATE		DELIVERY MODE		
05/22/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary

Application No.

10/081,953

Applicant(s)

HENNEN ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 10, 2009 has been entered. Claims 1-16 and 18-23 are pending and under examination.

Response to Amendment

2. The following rejections are withdrawn:
- The rejection of claims 1-16 and 18-23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of Applicant's amendment. The claims now recite, "the extract consisting of water soluble proteins of a yolk of an egg having molecular weights of about 8,000 Da or less, including transfer factor and other egg yolk proteins". The recitation of "other yolk proteins" seems redundant, however the deletion of "egg-specific" overcomes the new matter rejection.
 - The rejection of claims 1-16 and 18-23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of Applicant's amendment deleting the term in question

Claims Summary and Interpretation

3. The claims are drawn to a method for inducing a T-cell mediated immune response in an animal by administering a composition including an extract of an egg. Note that the term “including” is understood to be of the same scope as “comprising”. The composition comprises an extract of an egg and in addition to the extract may contain any other components, including components of an egg. The extract *itself* consists of water soluble proteins of a yolk of an egg having molecular weights of about 8,000 Da or less; transfer factor is present in the extract, as are other egg yolk proteins having the specified MW. The transfer factor is present in a concentration greater than that present in the egg. Note that this claim interpretation, regarding the components of the composition being administered, is different than in previous Office actions, thus the reinstatement of art rejections previously withdrawn.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 and 19-23 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dopson (PGPub 2002/0044942A1, “Dopson”, published April 18, 2002, with priority to provisional application 60/233,400, filed September 18, 2000), for reasons of record. Applicant

indicates in the response filed June 4, 2008, October 31, 2008 and April 10, 2009 that an affidavit may be filed once all other issues in this application are resolved.

5. (*Reinstated Rejection*) Claims 1-3, 7-13, 15, 16, and 18-23 are rejected under 35 U.S.C. 102(b) as anticipated by Lee (US Patent 5,367,054), evidenced by Kirkpatrick *et al.* (US Patent 5,470,835). The Office is aware that this rejection (or a similar one) was previously withdrawn in view of an amendment to the claims. Upon further consideration of the claims (as discussed above in the "Claims Summary and Interpretation" section, the composition comprises an extract of an egg and in addition to the extract may contain any other components, including components of an egg. If the claims were to be amended such that the composition's only egg yolk components were those having a MW under about 8,000 Da, this rejection would be withdrawn. As the claims are written, the "consisting of" language does not sufficiently limit the composition to the embodiment that Applicant may intend.

Lee discloses a method for isolating and purifying immunoglobulins or fragments thereof or other biologically active factors from non-immune or immune egg yolk extracts (abstract). Lee's immune eggs are collected from any egg-producing member of the avian, reptile, amphibian or fish family which have been immunized (col. 4, lines 58-63). The antigens that can be used to immunize the egg-producing subject include bacteria and other desired antigens for immunization (col. 8, lines 16-31). Although Lee does not mention the presence of transfer factor, one would expect transfer factor to be present in Lee's eggs because the subjects are exposed to antigens that are capable of inducing a T-cell mediated immune response. Further, amphibians, reptiles and fish are exposed to a plurality of natural antigens that are present in the

environment regardless of human-controlled exposure to antigens via vaccination. Lee teaches that the products purified from the eggs are for pharmaceutical purposes such as passive immunization or as a health food ingredient (col. 1, lines 29-33).

Although Lee does not mention transfer factor or its molecular weight, the presence of transfer factor in Lee's composition is expected because Lee immunized hens with antigens that induce a T-cell response, and collects the immunoglobulin from the immune eggs. The transfer factor present in Lee's egg composition is expected to have a molecular weight of about 3-5 kD because that is the weight of transfer factor according to Kirkpatrick *et al.* (col. 3, lines 16-18).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(*Reinstated Rejection*) Claims 4-6 are rejected under 35 U.S.C. 103(a) as obvious over Lee, evidenced by Kirkpatrick *et al.* (US Patent 5,470,835), as applied to claim 1, and further in view of Taylor (US Patent 5,001,225). The Office is aware that this rejection was previously withdrawn in view of an amendment to the claims. Upon further consideration of the claims (as discussed above in the "Claims Summary and Interpretation" section, the composition comprises an extract of an egg and in addition to the extract may contain any other components, including components of an egg. If the claims were to be amended such that the composition's only egg yolk components were those having a MW under about 8,000 Da, this rejection would be

withdrawn. As the claims are written, the "consisting of" language does not sufficiently limit the composition to the embodiment that Applicant may intend.

The teachings of Lee are summarized above. Lee is silent on the specific routes of immunization using the egg extract product. However, Taylor discloses general methods well-known in the art for vaccines and passive immunizations, such as parenteral, oral, intranasal, intravenous, intramuscular, topical or subcutaneous (abstract, column 15, lines 37-69, and column 16, lines 1-14). It would have been obvious to administer Lee's egg extract via the routes of administration disclosed by Taylor. One would have been motivated by Lee's teaching that egg extracts can be used in passive immunization (column 3, lines 31-40). One would have had a reasonable expectation of success that the administration of Lee's product via the routes disclosed by Taylor would have worked to elicit a T-cell mediated immune response in the recipient of the egg extract, because Lee's product contains transfer factor and the administration of transfer factor would elicit the T-cell response.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (5,367,054), evidenced by Kirkpatrick *et al.* (US Patent 5,470,835), as applied to claim 1, and further in view Dekich (*Poultry Science*, 1998, 77:1176-1180). The Office is aware that this rejection was previously withdrawn in view of an amendment to the claims. Upon further consideration of the claims (as discussed above in the "Claims Summary and Interpretation" section, the composition comprises an extract of an egg and in addition to the extract may contain any other components, including components of an egg. If the claims were to be amended such that the composition's only egg yolk components were those having a MW under about 8,000 Da, this rejection would

be withdrawn. As the claims are written, the “consisting of” language does not sufficiently limit the composition to the embodiment that Applicant may intend.

Lee is silent on specific viral antigens used to immunize egg-producing animals. However, Dekich discloses several diseases that are treated/prevented in the boiler industry. Respiratory diseases include Newcastle disease, infectious bronchitis and infectious laryngotracheitis (page 1177, first column). Passive immunization techniques have been used for all three diseases. One would have been motivated to immunize Lee’s egg-producing animals, such as chickens, with antigens associated with Newcastle disease because Dekich teaches that Newcastle disease is common among chickens. One would have been motivated by Lee’s suggestion that viral antigens can be chosen to hyperimmunize egg-producing animals (Lee, column 7, line 55, and column 8, lines 25-27). One would have had a reasonable expectation of success that the immunization of Lee’s egg-producing animal with Newcastle disease virus antigen would have resulted in a T-cell mediated immune response

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/
Primary Examiner, TC1600